

PATENT COOPERATION TREATY

LHP/JTP/Swahk

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITYTo:
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PCT

WRITTEN OPINION

(PCT Rule 66)

Date of Mailing
(day/month/year)

13 JUL 2004

Applicant's or agent's file reference

62611.000278

REPLY DUE

within 1 months/days from
the above date of mailing

International application No.

PCT/US03/30483

International filing date (day/month/year)

29 September 2003 (29.09.2003)

Priority date (day/month/year)

27 September 2002 (27.09.2002)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 31/20 and US Cl.: 514/560, 558

Applicant

MARTEK BIOSCIENCES CORPORATION

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.**When?** See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.**Also** For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6**If no reply is filed**, the international preliminary examination report will be established on the basis of this opinion.4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 26 April 2004 (26.04.2004).

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Form PCT/IPEA/408 (cover sheet)(July 1998)

WRITTEN OPINION

International application No.

PCT/US03/30483

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☒ the description:
 pages 1-28, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☒ the claims:
 pages 29-31, as originally filed
 pages NONE, as amended (together with any statement) under Article 19
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☒ the drawings:
 pages 1, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
 pages NONE, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 7,11-16,18 and 20-25

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 7,11-16,18 and 20-25 are so unclear that no meaningful opinion could be formed (*specify*):

Because they are improper multiple dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-6,8-10,17 and 19</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-6,8-10,17 and 19</u>	NO
Industrial Applicability (IA)	Claims <u>1-6,8-10,17 and 19</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-6,8-10,17 and 19 does meet novelty under PCT Article 33 (2).

Claims 1-6, 8-10, 17 and 19 lack an inventive step under PCT Article 33(3) as being obvious over Berge (U.S. Patent No. 6,365,628 B1). The claims are drawn to a method for improving glucose control, treating diabetes, and treating a patient at risk of developing metabolic syndrome comprising administering DHA and optionally a second pharmaceutical agent such as an anti-diabetic agent to the patient. Berge teaches administration of novel fatty acid analogues to treat diabetes and reduce the concentration of glucose in the blood, and treat multi-metabolic syndrome. It does not teach DHA specifically. It is prima facie obvious to substitute DHA, a fatty acid analog for the fatty acid analogues of Berge motivated by the teaching of Berge that fatty acid analogues, such as tetradecylthioacetic acid are successful in treatment of metabolic syndrome and diabetes. It does not teach co-administration with other known anti-diabetic agents. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.